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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

SITTON, JEHANNE SOUAYA

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 10/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/673,476	Applicant(s) COLE ET AL.	
	Examiner Jehanne S. Sitton	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 53-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 53-56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Currently, claims 53-56 are pending in the instant application. All the amendments and arguments have been thoroughly reviewed but are deemed insufficient to place this application in condition for allowance. The following rejections are reiterated. They constitute the complete set being presently applied to the instant Application. Response to Applicant's arguments follow. This action is FINAL.

Priority

2. It is noted that the Oath/Declaration in the instant application claims priority to US application 09/060,756, now US Patent 6,183,957, filed April 16, 1998. Further, in applicant's response dated 11/21/2003, at page 10, priority claim to such application was used to overcome a rejection applied under 35 USC 102(a) (reference applied was published June 1998). This information, however, is not contained in the first line of the specification or an AD sheet. (The examiner has reviewed the application history and could not find any amendment to add the priority claim).

If applicant desires benefit of a previously filed application under 35 U.S.C. 120, specific reference to the earlier filed application must be made in the instant application. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications. This should appear as the first sentence(s) of the specification following the title, preferably as a separate paragraph unless it appears in an application data sheet. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a

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patent, the expression “now Patent No. _____” should follow the filing date of the parent application. If a parent application has become abandoned, the expression “now abandoned” should follow the filing date of the parent application.

If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was

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unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Response to Amendment

3. In response to the requirement set for above, an amendment to the specification was submitted 9/8/2005. It appears to contain the following 2 errors:

1) This amendment appears to incorrectly claim the benefit of priority to PCT/IB99/00740 which designates the US. It is noted that the instant application was originally filed as the national stage application of such PCT, and it's filing date is the filing date of the international PCT application (see declaration filed 11/30/2000). See MPEP 1893.03(c) [2nd to last para before section 1893.03(d)]. It should also be noted that the original oath/declaration filed 11/30/2000 designated the instant application as a 371 application, but also incorrectly claimed priority to the '756 application under 35 USC 119. On 12/6/2001, a substitute oath/declaration was filed which corrected the claim for priority to the '756 application under 35 USC 120, but now does not designate the instant application as a 371 application and instead claims priority under 35 USC 119. Therefore, it is unclear if applicant's intended to change the status of the instant application from a 371 application to an application filed under 35 USC 111(a). Such discrepancy must be corrected. If applicant's intended the latter and the change in designation from 371 was correct, applicant should note the provisions of MPEP 189.03, 1895 and 1896, and chapter 200. It is also noted that in such case, the filing date of the instant application would be after November 29, 2000 and a petition would be required for the priority claim. See section 2 above. If the designation of the PCT application under 119 was incorrect in

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the declaration filed 12/6/2001, a new Oath or Declaration is required. It is also noted that the bibliographic ^{data} ~~date~~ for this application is also incorrect, and is missing reference to application 09/060,756, and may incorrectly designate the instant application as a 371 application.

2) Further, the reference to priority to US application 09/060,756, now US Patent 6,183,957, is also incorrect because such priority is claimed under 35 USC 120 and therefore must indicate relationship to the priority application (see above, and MPEP 1893.03 "Benefit Claim under 35 USC 119(e) or 120 and 365(c)".)

Accordingly, benefit of priority to the earlier filing date of 4/16/1998 is denied.

Claim Rejections - 35 USC § 102

4. The application fails to properly designate priority to the '756 application. The rejection made at section 9 of the office action mailed 5/21/2003, as now applied to claims 53-56, under 35 USC 102(a) is therefor maintained herein.

Response to Arguments

5. The response states that priority to the '756 application is claimed and that the specification has been amended to perfect the priority. This amendment, however is not sufficient for the reasons made in section 3 above.

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed.

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Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 53-56 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 9-11 and 13 of U.S. Patent No. 6,183,957. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are coextensive in scope. The overlapping subject matter is as follows. Instant claims 53-56 are drawn to purified polynucleotides comprising an open reading frame within SEQ ID NO: 1, as set forth in the claims. Claims 9-11 and 13 of the '957 patent are drawn to purified polynucleotides isolated by the specific hybridization method of claim 7. As defined by the specification of the '957 patent (which is identical to the specification of the instant application), the method of claim 7 of the '957 patent was used to isolate SEQ ID NO: 1 of the instant application (see instant specification, page 4, last para; page 10, 4th para; page 11, 2nd full para, and 6th full para; and page and page 13, beginning at 2nd para. See '957 patent: cols 3-4, and cols 7-20). SEQ ID NO: 1 is a 12.7 kb chromosomal fragment isolated from and unique to *M. tuberculosis* and contains 11 ORFs. Accordingly, the scope of the subject matter directed to claims 9-11 and 13 of the '957 patent and that of instant claims 53-56 overlap and are not distinct from one another. As stated in MPEP 806.05: "If nondistinct inventions are claimed in separate applications or patents, double patenting must be held, except where the additional

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applications were filed consonant with a requirement to restrict in a national application.”.

Further, MPEP 804 (IIB) states: “Further, those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent. In re Vogel, 422 F.2d 438, 441-42, 164 USPQ 619, 622 (CCPA 1970). The court in Vogel recognized “that it is most difficult, if not meaningless, to try to say what is or is not an obvious variation of a claim,” but that one can judge whether or not the invention claimed in an application is an obvious variation of an embodiment disclosed in the patent which provides support for the patent claim. According to the court, one must first “determine how much of the patent disclosure pertains to the invention claimed in the patent” because only “[t]his portion of the specification supports the patent claims and may be considered.” The court pointed out that “this use of the disclosure is not in contravention of the cases forbidding its use as prior art, nor is it applying the patent as a reference under 35 U.S.C. 103, since only the disclosure of the invention claimed in the patent may be examined.”

Response to Arguments

8. The response filed 9/8/2005 traverses the rejection. The response states a restriction requirement between methods and products was made in the ‘957 patent as well as the instant application and that the reasoning for the requirements was that the inventions were distinct from each other because the products could be isolated by a materially different process. The response concludes that it is impermissible to now reject these claims under obviousness type double patenting because the pending claims recite polynucleotides that the office contended were

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distinct from claims 9-11 and 13 in the '957 patent. This argument has been thoroughly reviewed but was not found persuasive. The restriction requirements cited by the response were made between method claims and product claims, not between claims 9-11 and 13 of the '957 patent and the instant pending claims. The conflicting claims are drawn to products, not methods. While the products of the '957 patent and the products claimed in the instant application can be made by different methods, the products themselves are coextensive in scope and not patentably distinct from each other. The products claimed in claims 9-11 and 13 of the '957 patent encompass a polynucleotide that is different between two different mycobacterium strains. SEQ ID NO: 1 is a 12.7 kb chromosomal fragment isolated from and unique to M. tuberculosis and contains 11 ORFs. Therefore, the claims of the instant invention and claims 9-11 and 13 of the '957 patent are coextensive in scope and not patentably distinct from each other. Therefore, the rejection is maintained.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. No claims are presently in condition for allowance.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Sitton whose telephone number is (571) 272-0752. The examiner can normally be reached Monday-Thursday from 8:00 AM to 5:00 PM and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (571) 272-0745. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Jehanne Sitton
Primary Examiner
Art Unit 1634

Jehanne Sitton
10/27/05